Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D0868280	05/12/2025
Name of Provider or Supplier	**Street Address, City, State**	
Medical Specialists Inc	305 Jones Avenue, Waynesboro, GA	

For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	A proficiency testing desk review was completed on May 12, 2025. At the time of the review, the laboratory was not in compliance with the Clinical Laboratory Improvement Amendments of 1988, 42 CFR 493.1 through 42 CFR 493.1780. The following condition deficiencies were cited: D2016 - 42 CFR 493.803 Condition: Successful participation [proficiency testing] D6000 - 42 CFR 493.1403 Condition: Moderate Complex Laboratory Director
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: Based on review of the CASPER 155 report and review of the American Proficiency Institute (API) reports, the laboratory failed to maintain satisfactory proficiency

	testing (PT) participation for Cell Identification (cell ID) in 2024 event 3 and for White Blood Cell Diff (WBC Diff) in 2025 event 1, resulting in an initial unsuccessful participation. Refer to D 2130
D2130	HEMATOLOGY CFR(s): 493.851(f) (f) Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on review of the Centers for Medicare and Medicaid (CMS) CASPER 155 report and review of American Proficiency Institute (API) reports, the laboratory failed to maintain satisfactory participation in two consecutive testing events (3rd event of 2024 and 1st event of 2025), resulting in an initial unsuccessful participation for Cell ID/WBC Diff. Findings: 1. A review of Casper Report 155 revealed the laboratory failed Cell ID/WBC Diff on the following: 2024 Event 3 Cell ID Score 47% 2025 Event 1 WBC Diff Score 60% 2. A review of the laboratory's API Reports confirmed the laboratory failed Cell ID/WBC Diff with the aforementioned scores.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on review of the CMS CASPER 155 report and review of American Proficiency Institute (API) reports, the laboratory director failed to provide overall management and direction for proficiency testing performance. The laboratory director failed to ensure proficiency testing samples were tested as required. Refer to D6016
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) (e)(4)(i) The proficiency testing samples are tested as required under Subpart H of this part; This STANDARD is not met as evidenced by: Based on review of the CMS CASPER Report 155 and the American Proficiency Institute (API) 2024 event 3 and 2025 event 1 PT evaluation reports, the laboratory director failed to ensure successful proficiency testing performance in 2 consecutive testing events (2024 event 3 and 2025 event 1), resulting in the initial unsuccessful participation for Cell ID/WBC Diff..